K131585

510(k) Notification Submission – Traditional
Intel-GE Care Innovations™ QuietCare®-Networked

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel-GE Care Innovations™
Address:	3721 Douglas Boulevard, Suite 100, Roseville, CA 95661
Telephone:	(916) 847-7794
Contact Person:	Maureen Glynn
Date Prepared:	May 23rd, 2013

OCT 08 2013

Device Information

Trade Name:	Intel-GE Care Innovations QuietCare-Networked
Common Name:	Bed-Patient Monitor
Classification Name:	Bed-Patient Monitor (21 CFR 880.2400, Product Code KMI, Class I)

Substantial Equivalence is claimed to the following devices:

1. MobileCareb Monitor™ from AFrame Digital Inc., (K090138)
2. Wireless MedCARE LLC VivaTRAK (K101109)

Device Description

Care Innovations QuietCare-Networked uses advanced motion sensors to monitor Activities of Daily Living for senior residents who require care assistance. It provides alerts and reporting information to care givers when conditions or trends are detected that indicate the senior resident may need care intervention.

Indications for Use

QuietCare-Networked is intended for use in monitoring the environmental conditions and activity (motion) of an individual living in a senior housing community. QuietCare-Networked recognizes and monitors certain patterns of activity including but not limited to bathroom and bedroom activity, residence entry/exit, and interaction with food and medication storage.

Caregivers are provided with information and notification about the occurrence of, and changes in, these monitored activity patterns and environmental conditions. Noteworthy occurrences and changes are communicated to caregivers through direct notification (pager, voice alert, email) as well as a secure Internet website.

Data from QuietCare-Networked should not be relied on as medical advice or clinical diagnosis. Caregivers should always rely on licensed medical professionals in making all health decisions and should use the information provided by QuietCare as a resource in that process.

Caregivers should not rely solely on the use of QuietCare-Networked for care management of clients/residents. Caregivers should use standard care practices established within their care organization to ensure the safety and wellness of senior clients/residents.

QuietCare-Networked is available for over-the-counter use.

Technological Characteristics

QuietCare-Networked is substantially equivalent to the predicate devices in terms of software functionality, method of data collection, sensor types, communication methods, connectivity, communication protocol, and display method.

Safety and Efficacy

The Intel-GE Care Innovations QuietCare-Networked device does not rely on an assessment of clinical performance data. The data within this Premarket Notification demonstrates that there are no significant differences between this device and the predicate. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

Conclusion

The information in this Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the predicate devices already in commercial distribution. Equivalence is demonstrated through intended use, design and testing methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2013

Intel-GE Care Innovations
Ms. Maureen Glynn
3721 Douglas Boulevard, Suite 100
ROSEVILLE CA 95661

Re: K131585
Trade/Device Name: Intel-GE Care Innovations QuietCare-Networked
Regulation Number: 21 CFR 880.2400
Regulation Name: Bed-Patient Monitor
Regulatory Class: I
Product Code: KMI
Dated: August 27, 2013
Received: August 30, 2013

Dear Ms. Glynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Notification Submission – Traditional
Intel-GE Care Innovations™ LLC
Intel-GE Care Innovations™ QuietCare®-Networked

Indications for Use:

510(k) Number: K131585

Device Name: Intel-GE Care Innovations™ Guide

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Prescription Use _____ AND/OR Over-The-Counter Use ____X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Richard C. Chapman
2013.10.08 11:22:25
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)